PD4 Exh 15

DEA Compliance Manual

Cardinal Health

DEA
COMPLIANCE MANUAL

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PREFACE

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drugs and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Prevention Control Act of 1970 (the "Controlled Substances Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The thrust of this Controlled Substances Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- recordkeeping requirements;
- manufacturing quotas;
- distribution restriction;
- dispensing restrictions;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable by up to 15 years imprisonment and $10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

This manual is intended as a resource to the Controlled Substances Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs
Part 1300 to End -- *available from:*

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual -- *available from:*

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INTRODUCTION

The Controlled Substances Act and implementing regulations (21 CFR 1300 to the end) impose a substantial number of requirements upon wholesalers and other handlers and prescribers of controlled drugs. This training manual deals with the records of controlled drug transactions that must be kept by wholesalers and the reports that wholesalers must submit. The theory behind the records requirements for Schedule III through V controlled drugs is that a registrant's regular, normal business records are acceptable **provided** that they contain all necessary elements of information and that these elements are readily retrievable from the records (more later on retrievability). Special, separate records are required from Schedule II controlled drugs (see Biennial Inventory and Order Forms). The importance of accuracy in taking required inventories and in recording controlled substances transactions should be stressed to wholesaler employees charged with these responsibilities.

INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand in live, morgue and brokerage.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Changing Inventory Date. To coincide with a fiscal year, year-end ARCOS inventory, general inventory time, or any other reason, the wholesaler may change the controlled drug inventory date to another fixed date provided that the new is within two years of the previous biennial date. DEA does not have to be notified.

Cardinal Health had received prior authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years and will continue to do so. Refer to DEA correspondence 11/21/96.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand in live, morgue and brokerage.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

Periodic
(21 CFR 1304.11, 21 CFR 1301.74)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements
Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. **(21 CFR 1304.11 (d))**

> *Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.*

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

> *Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.*

Required Inventory Records. The inventory must be maintained in written, typewritten, or printed form. It should be signed by those taking the count and both the date of the inventory and whether it was taken as of the opening of business or close of business must be recorded. Inventories of all Schedule I (research drugs) and Schedule II substances must be separated from inventories for all other substances. Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner. Readily retrievable means that the records (whether ADP, electronic, or mechanical are kept in such a manner that they can be separated out in a reasonable time and/or the items are identifiable visually from other items appearing on the records (asterisk, redlined, etc.).

For each controlled substance in finished form, the required inventories must contain:

- Name of the substance;
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter;
- Number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- Number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

For controlled substance returns, damaged goods, or substances awaiting disposal, the inventory must contain:

- Name of the substance;
- Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form; and
- Reason for the substance being maintained by the registrant.

(21 CFR 1304.22 (b), 21 CFR 1304.11(2))

Count Requirements. When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Retention of Inventory Records. The records must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. **(21 CFR 1304.04)**

Note: State record keeping requirements may be more than two years and should be maintained accordingly.

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). **(Refer to DEA Correspondence 8/25/93).** The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA **Certificate of Registration (Exhibit J).** DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration **(Exhibits K, L).** A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The **Quarterly DEA Exception Report (Exhibit N)** is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office **will** check this type of situation. Calls to the local DEA office should be documented on a **Regulatory Agency Contact Form (Form #1).**

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a **Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.**

Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. **(21 CFR 1301.51)**

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. **Refer to DEA Correspondence 8/25/93.**

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

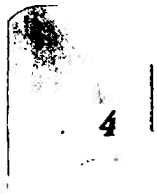
W - Manufacturer

Y - Distributor

V - Retail Distributor

X - Importer

Z - Exporter



MAINTENANCE OF RECORDS

The wholesaler is required to maintain on a current basis a complete and accurate record of every controlled substance received, distributed, or otherwise disposed of. Separate records are required for each registered location. Records of Schedule I (research drugs) and II drugs must be maintained separately (see section on Order Forms). All required records must be retained for two years. **(21 CFR 1304).**

Required Record Information

(21 CFR 1304.22 (b))

The following information is required for each controlled substance:

- Name of the substance.
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- Number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

  Note: Many wholesalers have been cited for failing to record the actual date of receipt on the document of transfer (e.g., invoice or packing slip) as well as the accurate name, address and registration number of the shipper.

- Number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed.

  Note: Wholesalers also have been cited for failing to record the actual shipping date as well as the accurate name, address, and registration number of the person to whom it was shipped. Ditto marks on DEA Form 222 are not acceptable for recording dates.

  Note: When providing backup service for another division, and shipping directly to the division's customer, your records must show that

customer as the recipient of the product. **Refer to DEA Correspondence 6/28/95.**

- Number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed of.

Automated Records Systems

Federal requirements can be met by either automated or manual records systems provided that the specific system contains all the necessary data elements. The wholesaler has the option of maintaining records for Schedule III through V transactions either separately or, if they are readily retrievable, with noncontrolled drug transactions. Ready retrievability requires that the records (whether an automated system, a manual system or a combination) clearly identify controlled drug transactions so that they can be extracted readily (i.e., identified by schedule symbol (C-III) or asterisk, redlined, on separate invoices for controlled drugs only, etc.).

Returns from Customers or to Manufacturers

Care must be taken to ensure that all the data elements are included on records for returns. These records must have the same information as that required on all receiving/shipping records including the name, address, and registration number of the customer/supplier, the name of the substance, each finished form, the number of units or volume and the number of containers; and the **actual** date the substance was received by the wholesaler or returned to the supplier. Schedule II returns must be made pursuant to a valid order form (see section on Order Forms).

Note: Wholesalers often fail to place the required information on return documents or to maintain Schedule III through V returns records in a readily retrievable manner.

Rules for Central Record Keeping

(21 CFR 1304.04)

Recognizing the trend toward the automation of business records in a central data center covering multiple locations, DEA allows financial and shipping records to be kept at a central location following written notification to the DEA special agent in charge of the field office covering the area where the registrant is located. The central records system may commence 14 days after the special agent in charge receives notification (sent in triplicate by certified or registered mail, return receipt requested). The notification must contain the name, address, and registration number of all locations to be included, the name and address of the exact location where the central records will be kept, a brief description of the records system and the records to be maintained centrally, and a statement agreeing

to make the records available at the registered location within two business days. If there is no response from DEA within 14 days after receipt by the special agent in charge, the wholesaler can proceed with the central records system. The wholesaler must, if DEA chooses, allow inspection at the central location in lieu of delivery to the registered location.

Exception: Inventories for all schedules of controlled drugs and Schedule II order forms must be kept at the registered location.

ARCOS participants wishing authorization to report from other than their registered location must obtain a **separate** central reporting identifier from the ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005, (202) 307-8600.

Microfilm/Microfiche Records

DEA does not consider copies of primary records an acceptable substitute for primary documents due to the opportunity for alteration when copying an original document. However, DEA will consider for approval on a case-by-case basis any system that simultaneously generates the copy and the original record. Approval of such a system requires DEA access to readers and printers as well as to the film. If a wholesaler microfilms/microfiches the originals for ease of handling, but retains the originals in backup storage for two years, this would satisfy DEA concerns as the originals could be made available for review as needed.

Drop Shipments of Controlled Substances

Wholesaler records of drop shipments are not required because these controlled substances are shipped directly from the supplier to the customer and never enter the wholesaler's possession. All such purchase orders and invoices must be clearly marked as drop shipments and should not be stored with records that document the actual receipt or distribution of controlled substances. Further, Schedule III narcotic substances which are drop-shipped are ARCOS reportable by the supplier on DEA Form 333.

Storage of Records

Care should be exercised to ensure that, for at least the two years they must be retained, all the wholesaler's controlled substances records are maintained in a secure and yet accessible manner. The controlled substance records are as follows:

- Receiving documentation
- Invoices and credit memos
- Narcotic Sales Report
- Narcotic Order Forms (DEA Form 222), brown and blue copies, and related records
- Monthly ARCOS Report
- ARCOS Edit Error Report and submission

- Count Sheets from Periodic Inventories
- Suspicious Order Analysis, or Excessive Purchase Report
- DEA Form 106
- DEA Form 41
- Return Receipt Requested forms for any mailings
- Debit Memos for Returns to Vendors
- Year-End ARCOS Inventory
- Biennial Inventory

DEA requires that records be maintained for two years. Record retention requirements for individual states may vary. Additional records may be maintained as required by division policy.

Shipping Errors

Shipping errors must be documented as any normal transfer of controlled substances would be and as mandated by DEA record keeping and reporting requirements. In other words, any transfer of controlled substances, regardless if shipped in error, must be appropriately documented with 222s, invoices, credit memos, and ARCOS reporting as applicable. The swapping of the right product for the wrong product is inappropriate. Each distribution and return must be documented as a separate independent transaction. These requirements apply to intra-company as well as customer shipments. Several examples of shipping error scenarios and the corresponding corrective actions are included as Exhibit Q.

Brokerage Operations

Some Cardinal Distribution facilities have brokerage business operating within their distribution center. The brokerage business operates on the division's DEA registration number, therefore the division is ultimately responsible for compliance with DEA regulatory requirements as they apply to brokerage operations. Key compliance issues related to the division/brokerage operating relationship are as follows:

- Brokerage personnel must coordinate with division personnel to ensure they are following all division procedures related to the receipt, distribution, storage, inventory, etc. of controlled substances.
- All transaction records and reports for brokerage purchases, sales and other dispositions of controlled substances must be included in the division's records. On the distrack system this is accomplished through a month end records transfer from the brokerage system to the division system. HP divisions maintain hard copy records and adds ARCOS records through a manual process.
- Records for controlled substance transactions between brokerage and the division are not required records since brokerage operates on the division's DEA registration. These records must be deleted from the brokerage and division record keeping systems.

- Brokerage controlled substance inventory must be stored in the cage and vault, but is maintained separately from the division's inventory and is identified as brokerage inventory.
- Although brokerage inventory is maintained separately, it must be included in all inventories conducted by the division.
- The division must be licensed, as required, in those states into which they distribute to brokerage customers.
- The division must verify and maintain a copy of all brokerage customer DEA registrations and state licenses.

A more detailed description of brokerage operations is contained in the **Brokerage Warehouse Operations Procedures Manual** which should be available to you from brokerage personnel located in your division.

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ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the **DEA Narcotic Blank Log (Form #4),** and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.

- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.

- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to **21CFR 1305.05(c).** The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

  Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log.**
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log.**

- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations **(21 CFR 1305.06).**
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

  Note: All three copies of voided order forms must be sent to the division.
- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3),** signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

  Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. ***Refer to DEA Correspondence 07-18-96.***

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green)the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.

- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.

- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

  Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

  Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. **Refer to DEA Correspondence 6/29/92.**

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution

center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit,** under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. **Refer to DEA Correspondence 07-18-96 and 08-28-96.**

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.

2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.

3. Cardinal crossdock employee removes 222s from envelopes and **completes DEA222 Transmission Log** (Form #5).

4. Cardinal employee faxes 222s to distribution center. **This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.**

5. Fax is received in distribution center by Operations Manager or designee.

6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.

    a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.

7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.

8. Operations Manager or designee delivers faxed 222s to the vault.

9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.

2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.

   a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.

3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.

4. Operations Manager or designee delivers faxed 222 to the vault.

5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

- The supplier retains copy 1 (brown) of each order form that has been filled.

- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to **(21 CFR 1305.06 (d))** must be kept at the registered location printed on the order form.

  Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms

(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:

  (1) Is not complete, legible, or properly prepared, executed, or endorsed; or

  (2) Shows any alteration, erasure, or change of any description.

- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with **21 CFR 1305.13**. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.

- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.
- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.

- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.
- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code numer is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.

- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification (Form #6).** The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown)and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with **21 CFR 1305.09(b),(c) and (d)** including shipping all substances directly to the purchaser.

- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is

requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (bue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to **21 CFR 1301.45** or **1301.46** of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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METHAMPHETAMINE CONTROL ACT RECORDKEEPING AND REPORTING REQUIREMENTS (21 CFR 1310)

Pursuant to the Domestic Chemical Diversion and Control Act, DEA has regulated both RX and OTC single-entity ephedrine products since 1994. The Methamphetamine Control Act of 1996 extends these regulations and DEA control to the distribution of OTC combination ephedrine, pseudoephdrine and phenylpropanolamine products. A list of these products covered by the regulations is included as **Appendix E.**

The requirements which became effective October 3, 1997 are not the same as those for controlled substances. These products will not be scheduled, will not have to be kept in secure storage, and complete inventory accounting and ARCOS reporting requirements do not apply.

The MCA regulatory scheme, described in 21 CFR, Part 1310, has four basic components: registration; keeping records of ephedrine, pseudoephedrine and phenylpropanolamine transactions; reporting any unusual losses or excessive purchases to DEA, and taking steps to be sure the purchaser is legitimate.

Registration

Distributors who handle covered products are required to register as a chemical distributor with DEA, however DEA has exempted anyone with a valid DEA controlled substance registration from having to obtain the additional registration.

Your customers should have either a DEA controlled substance registration or a chemical registration.

Please note that there is a pseudoephedrine and phenylpropanolamine registration exemption for customers who meet the definition of a "retail distributor." Retail distributor is defined as a grocery store, drug store or other entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use (approximately 1200 dosage units), both in number and volume of sales, either directly to walk-in customers or in face to face transactions by direct sale.

The exemption process should be handled on a case by case basis. Customers not currently registered with DEA who believe they qualify for the exemption should be requested to provide written documentation to this effect. Once the documentation is received, the customer can be set up to purchase these items.

Note: A review of Cardinal's customer database has indicated that the vast majority of customers currently possess a valid DEA registration. Additionally, customers who do not possess such a registration are of a class that would not typically purchase these products.

Records

You must maintain readily retrievable records of each ephedrine, pseudoephedrine or phenylpropanolamine product transaction for 2 years. Normal business records shall be considered adequate, as long as they contain:

- the name and address of each party to the transaction
- the date of the transaction
- the name, quantity, and form of packaging of the ephedrine or pseudoephedrine product
- the method of transfer
- the type of identification used by the purchaser.

Reports

You must report to your local DEA office:

- Any unusual ephedrine, pseudoephedrine or phenylpropanolamine transaction -- extraordinary quantity, uncommon method of payment or delivery, or any other suspicious circumstances
- Any unusual or excessive loss of ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories
- Any proposed transaction with a person DEA has requested in writing that you monitor (report **before** completing the sale).

Note: a transaction may not be completed with a person identified by DEA unless approved by DEA. Steps should be taken to prohibit sales to these persons.

Reports are to be made orally, whenever possible, to the local DEA office at the earliest opportunity and as much in advance of the sale as possible. A written report must then be filed within fifteen days of becoming aware of the above circumstances. Written reports must contain the same information as the required records, plus the telephone number of the other party, if possible, and a description of the circumstances leading you to make the report. Written reports should be made on the **MCA Transaction Report (Form #8).**

Identifying the Customer

The regulations require the wholesaler to "identify the other party" to the transaction. In general, an ongoing agreement with your customer, an account that you had for some time, and other such business relationships indicating you know your customer, should establish the kind of verification DEA is looking for. Credit applications and Dun and Bradstreet reports should be sufficient.

Compliance Guidelines

- Verify that your customers are registered to purchase these products or are exempt from the registration requirement.
- Maintain required records (normal business records are sufficient if they contain the required information).
- Generate and review monthly the MCA dosage limit report (Exhibit R). Submit these reports to DEA.
- Report to DEA any unusual or excessive loss or disappearance of any ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories.
- Maintain a file consisting of any reports submitted to the DEA and the monthly Excessive Purchase Report.

Other Regulated Products

The requirements for ephedrine, pseudoephedrine and phenylpropanolamine also apply to other chemical products which wholesalers do not usually stock or stock and distribute in limited quantities. The recordkeeping and reporting requirements for these items, which are listed below, only apply when threshold limits set by the regulations are exceeded. A past review of sales history for the items that are stocked in certain Cardinal Distribution Centers indicated that typical distribution quantities do not come close to meeting these limits. However, division management should be aware of all regulated products in the event that DEA addresses this issue during an audit.

List I Chemicals:		
	Chemical	Threshold by base weight
1	Anthranilic acid and its salts	30 kilograms
2	Benzyl cyanide	1 kilogram
3	Ergonovine and its salts	10 grams
4	Ergotamine and its salts	20 grams
5	N-Acetylanthranilic acid and its salts	40 kilograms
6	Piperidine and its salts	500 grams
7	3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms
8	Methylamine and its salts	1 kilogram
9	Ethylamine and its salts	1 kilogram
10	Propionic anhydride	1 gram
11	Isosafrole	4 kilograms
12	Safrole	4 kilograms
13	Piperonal	4 kilograms
14	Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume).
15	Benzaldehyde	4 kilograms
16	Nitroethane	2.5 kilograms

List II Chemicals:			
Imports and Exports			
	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
(B)	Acetone	500 gallons	1,500 kilograms
(C)	Benzyl chloride	N/A	4 kilograms
(D)	Ethyl ether	500 gallons	1,364 kilograms
(E)	Potassium permanganate	N/A	500 kilograms
(F)	2-Butanone (MEK)	500 gallons	1,455 kilograms
(G)	Toluene	500 gallons	1,591 kilograms

Domestic Sales			
	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
(B)	Acetone	50 gallons	150 kilograms
(C)	Benzyl chloride	N/A	1 kilograms
(D)	Ethyl ether	50 gallons	135.8 kilograms
(E)	Potassium permanganate	N/A	55 kilograms
(F)	2-Butanone (MEK)	50 gallons	145 kilograms
(G)	Toluene	50 gallons	159 kilograms

Note: The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

	Chemical	Threshold by volume	Threshold by weight
(A)	Hydrochloric acid	50 gallons	.....
(1)	*Anydrous hydrochloric acid*	.....	*27 kilograms*
(B)	Sulfuric acid	50 gallons	.....

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REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

- **ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:**

  DEA Headquarters
  Attn: ARCOS Unit
  2401 Jefferson-Davis Highway
  Alexandria, VA 22301

- **ARCOS reports sent via the U.S. Postal Service must use the following address:**

  Drug Enforcement Administration
  ARCOS Unit
  P.O. Box 27273
  Washington, D.C. 20038-7273

Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual **ARCOS OCR Form - DEA Form 333 - (Form #9).**

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on **Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10).** Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

> *Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.*

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. **Refer to DEA Correspondence 8/12/94 for additional information.**

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. **Refer to DEA correspondence 11/17/97.**

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

INTRODUCTION

Security is defined as the elements necessary to deter burglary or theft of controlled substances at a level of effectiveness that equals or exceeds federal regulations applicable to wholesaling. The elements include:

- Physical structures and barriers such as safes, vaults, cages, barricades, grilles, gates, fencing, locks and lighting;
- Electronic systems including burglary detection sensors and controls, emergency (holdup) signal devices, closed-circuit TV surveillance and recording equipment, access control systems, and communications devices; and
- Practices and procedures applicable to the installation, maintenance, inspection, testing and supervision of interrelated security devices and systems.

This section of the manual is provided to educate employees about DEA security requirements and to assist Division Management in evaluating compliance with these requirements.

In evaluating the overall effectiveness of a wholesaler's security against theft and diversion, DEA may consider, in addition to those security requirements previously discussed, any of the following factors:

- The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- The quantity of controlled substances handled;
- The location of the premises and the relationship such location bears on security needs;
- The type of building construction comprising the facility and the general characteristics of the building or buildings;
- The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- The type of closures on vaults, safes, and secure enclosures;
- The adequacy of key control systems and/or combination lock control systems;
- The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

- The adequacy of supervision over employees having access to manufacturing and storage areas;
- The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- The availability of local police protection or of the registrant's or applicant's security personnel, and;
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

9

PHYSICAL SECURITY - GENERAL WAREHOUSE

Management must insure that appropriate physical security measures are taken against the loss of company property and assets. The standards set forth in this section will assist in insuring reasonable protection of the company's assets.

Security of Design and Layout

In all cases of security planning, either for new construction or updating of current facilities, assistance should be requested from the Corporate Compliance Department.

It is suggested that management implement basic physical security designs from a **Security In-Depth Approach.**

In considering the design of a facility, use of all available resources in an efficient manner should be taken into consideration in order to achieve adequate protection for the facility. Emphasis should be placed on the operational requirement of the facility to determine the type and extent of physical security needed.

Protecting a drug warehouse in this day and age is a difficult task. Some of the factors to be taken into consideration when setting up an in-depth security protection system are:

- The exact function to be performed at that location
- The environment - political - economic - legal - terrain
- The vulnerability
- The area (geographic, neighborhood)
- The cost involved
- The possible future changes in the operation

The degree of protection should be predicated on what affect the loss would have on the operation and the relevant importance of the operation to the total business. Additionally, consideration should be given to the degree of susceptibility the operation has to outside threats. These threats are acts or conditions that may result in:

- Disruption of the facility
- Damage, loss or destruction of property
- Personal injury or loss of life
- Compromise of critical information

Threat severity depends on such variables as:

- Type of facility

- Function performed (distribution of drugs)
- Physical layout and construction
- Geographical location
- Stability of location
- Existing state of law and order
- Protection measures already in affect, if any

Perimeter Barriers

Perimeter barriers may be used to define the physical limits of a facility. They are used generally to restrict, channel or impede access. In addition, they offer two important benefits; create a psychological consideration and have a direct impact on the number of security posts that may be needed. The two major categories of barriers are natural and structural. the one most commonly used is fencing. When practical to do so, all facilities should be fenced. This action will provide a first line of defense against the criminal element.

- Fencing should be of the No. 9 gauge or heavier fabric. The mesh openings should not be larger than two inches. To prevent individuals from going under the fence, a cement apron not less than six inches thick can be installed under the fence. The top of the fence should contain an anti-climb overhang or barbed wire, installed at a 45 degree angle outward, consisting of three strands of barbed wire. In some instances, it may be desirable to employ an additional strand of razor ribbon which is interwoven between the strands of the barbed wire on the top of the fence.

- Gates, entrances and other openings in a perimeter barrier should be limited to the number necessary for efficient and safe operation of the distribution center.

- All fence lines should be cleared areas and be free from obstruction. The area should be cleared of weeds, rubbish, or other material capable of offering cover or assistance to an intruder attempting to climb, cut through, or tunnel under.

- Exterior doors may be an inviting entrance for an intruder because of convenience. The vulnerable points at the door are the frame, hinges, door panels and the lock.

- Doors should be installed so that the hinges are located on the inside. If this is not possible, the hinges should be installed so as to prevent their removal and the exterior pins should not be removable. The hinges that are on the exterior of the doors should be welded, brazed, or otherwise secured.

- Doors should be of metal or solid wood construction.

- Glass exterior doors should be equipped with decorative metal bars or be of the type of glass which resists breakage.

- Rolling overhead doors not controlled or locked by electric power should be protected by slide bolts on the bottom bar on the inside and padlocked when not in use.

- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a deadbolt lock with at least a one-inch (1") throw. These deadbolt locks should be protected by a case-hardened steel sleeve. This sleeve should cover the deadbolt throw and any other locking mechanism (e.g. electronic strike) on the door.

- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a wide-angle peep-hole. This mechanism will give employees a view of anyone requesting entry into the distribution center from the outside. If there is any doubt about the person's identity, then that person should be informed to report to the front door of the distribution center.

- Employees at the distribution center should not be allowed to park within fifty feet (50') of either the shipping door(s) or the receiving dock. When parking is limited at the distribution center, then it should be a standard rule that employees that work in these areas do not park near their respective work areas.

- There should be absolutely no markings on the distribution center identifying it as a drug warehouse. This includes signs over both the shipping and receiving doors or decals associated with drug associations attached to the glass on the distribution center.

- Utility boxes which are located on the exterior of the distribution center should be equipped with a padlock. If the utility company requests it, they should be issued a key to this box.

- For distribution centers which warrant it, closed circuit television should be installed on the exterior of the distribution center. The monitors for these cameras should be placed in strategic locations throughout the distribution center. The Corporate Compliance Department should be contacted prior to application of closed circuit television cameras.

- Shrubbery, trees and bushes should be trimmed down so that they are not above window level at the distribution center. Any exterior design, such as brickwork, latticework, or an exterior ladder should be removed from the exterior of the distribution center. These elements provide direct access to the roof of the building.

Protective Lighting

This safeguard has considerable value as a deterrent to thieves and vandals or any unauthorized entry. It is an essential element of an **In-Depth Security Program.** Requirements for protective lighting at facilities will depend on the situation and the areas to be protected.

Each situation requires careful study in order to provide the best visibility that is practical for such security functions as prevention of illegal entry, detection of intruders, inspection of vehicles, and illumination for distribution center employees exiting at night.

- Plan protective lighting to assure adequate illumination to discourage or detect attempts to penetrate an area, and reveal the presence of unauthorized persons within the area.

- Light sources should be located to insure that illumination is directed toward probable courses of intruders.

- Shadowed areas caused by structures near or adjacent to vital areas should be illuminated.

- Design should provide for overlapping light distribution.

- Exterior areas which should receive consideration are fenced perimeters, gate access areas, entrances to the distribution center, and any outside storage areas.

- Emergency power should be included for critical lighting; controls and switches should be locked.

- Lighting in unattended areas can be controlled by time clocks or light sensor equipment.

- The lighting at the distribution center should be checked by a member of the management staff at the distribution center on a routine, periodic basis. Lighting which is not operating properly or is out completely should be repaired immediately.

Locks and Key Control

Locks are the most generally utilized security device. The lock is most commonly used in protecting installations and activities, personnel, classified information, and company property. It should be noted that regardless of their quality or cost, locks should be considered delay devices only and not positive bars to entry. Locks, therefore, must be supplemented, where appropriate, with other security and protection devices and combined into the Security In-Depth Approach.

- The distribution center should have a Lock and Key Control System. It should be a standard practice at the distribution center that the exterior door locks, along with the cage day-gate, vault day-gate, and the combination to the vault be changed on an annual basis, or when an employee having access to the keys to these locks and/or the combination to the vault leaves the company's employ or is transferred to a new location.

- The key to the front door of the distribution center should **never** be the same as the key to the warehouse. The cleaning crew, alarm company, and the police department should not have a key to the distribution center.

- A **Key Log (Form #12)** should be maintained or a **Key Receipt (Form #13)** should be issued for each key distributed at the distribution center. A copy of the key receipt

goes to 1) the employee; 2) the distribution center manager; and 3) a copy is placed in the employee's personnel file. If an employee is entrusted with a passcard, then that number should also be placed on the key receipt form. Additional Key Receipt forms may be obtained from the Corporate Compliance Department.

- Spare keys to the distribution center, cage, or the combination to the vault should be kept in a secured location at the distribution center. These keys should be kept on the person of the employee entrusted with their care, or they should be kept on a locked desk drawer or small locked cabinet.

- A spare key to the vault should be secured inside the vault in an inconspicuous location. This key should be utilized in case distribution center employees are placed in the vault during the course of a crime.

- Padlocks which are utilized at the distribution center should always be left in the locked position when not in use. The serial numbers on these padlocks should be removed.

10

STRUCTURAL SECURITY

Schedule II Controlled Substances
(21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations **(21 CFR 1301.72(b))** provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in **1301.72(b)(4)(ii-iv)** and Section **1301.72 (b)(3)(ii)(a)(b)**, which read as follows:

21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;

- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of **21 CFR 1301.72(b) (3)(ii).**"

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination

- The controlled substance section also provides:
  The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

  Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by **21 CFR 1301.72(b)** *provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.*

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.


11

ALARM SYSTEMS

The alarm system at the distribution center should be one which provides telephone line security. Of the phone lines leading into the distribution center are compromised or cut, then this action should result in an immediate alarm at the distribution center. The police should then be notified immediately.

Any opening more than ninety-six square inches on the exterior of the distribution center should be added to the alarm system. These openings include air vents, roof hatches, skylights, etc.

The alarm equipment surrounding the cage and vault should be walk-tested at least once a month. Any equipment failures should be corrected immediately. The **Monthly Alarm Walk Test Report (Form #14)** should be completed and filed or distributed accordingly.

Schedule II Controlled Substances

The vault at the distribution center should be on a separate alarm system. This should be a stand-alone system with the following minimum security requirements:

The walls or perimeter of the vault are equipped with an alarm that includes standby power sources. When unauthorized entry is attempted, the alarm transmits a signal over a supervised alarm transmission circuit directly to a central station protection company; a local or state police agency that has a legal duty to respond; a 24-hour control station operated by the registrant; or such other protection as the administrator may approve.

The door of the vault is equipped with contact switches, and the vault has one of the following:

Complete electrical lacing of the walls, floors and ceilings; sensitive ultrasonic, microwave or passive infrared equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the administrator.

Additional motion detectors should be positioned directly outside and along the approach to the vault. These motion detectors should be able to pick up anyone approaching the vault when the alarm is set.

If necessary, due to local conditions or other problems, hold-up buttons shall be placed at strategic points of entry to the perimeter area of the vault.

Schedule III, IV, and V Controlled Substances

DEA regulations applicable to the security of Schedule III through V controlled substances state that the cage shall be equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administration may approve.

A cage is protected by motion sensing devices that are positioned or mounted outside (around) and over the cage to detect an intruder prior to an attempt to enter the cage area.

The cage door(s) is equipped with an alarm contact switch.

Alarm Related Security Procedures

The cage and vault alarm system is tested at least **annually** by the alarm contractors. At that time, the alarm contractor is required to perform a **complete on-site inspection,** test and adjustment of the entire alarm system and to replace any components, sensors or wiring that are defective. The alarm contractor confirms, in writing, the results of this inspection, certifying that the system at the time continues to meet the contractual obligations between the company and the alarm contractor and any applicable UL certification standards.

Division management conducts monthly tests of the vault door alarm contact switch as well as any motion sensing or capacitance devices used in conjunction with vault protection. A log is maintained showing the dates of the tests performed, any defects, the date the alarm company was advised of the defect, and the date the problem was corrected.

Such records are maintained on file for 24 months for review by any DEA agent.

Instructions to the alarm company provide that in response to alarm signals, trouble signals, loss of line security or open telephone circuits, the alarm company will promptly respond to the facility, contact the police, if required, and notify division management as designated on a letter of instruction provided by the wholesaler.

Upon notification by the alarm company of the receipt of a signal condition described above, the designated supervisor identifies the caller, confirms that alarm company guards have been dispatched and the police notified, and then proceeds to the premises.

> *Note: Return call verification to the alarm company should be made any time Cardinal personnel are requested to appear at the premises.*

On arrival, the supervisor verifies the presence of the police and/or the alarm company personnel at the site or if such is not the case, continues in his/her vehicle to a safe telephone location where the supervisor calls the police and/or the alarm company to arrange for their coincidental arrival at the premises. In some instances, it may be necessary for the supervisor to proceed to the police station in the vicinity to request a safe escort to the site.

If only alarm company personnel are present at the supervisor's time of arrival, their identity should be visually confirmed and a request made for the guard to radio his/her office to recall the police. The supervisor and the alarm company should remain outside the premises until the police arrive.

The supervisor should then unlock the entrance door, turn on designated lighting, admit the police and the alarm company personnel, relock the entry door, and then remain in the safest possible area until the police and the alarm company guards have completed their search of the premises.

When entering the premises area, the company supervisor or the alarm company guard should open alarm system protected areas that must be entered in order to search the premises and arrive at the controlled substances vault.

When a search is completed and it has been determined that there is no forced entry or other emergency condition, the company supervisor assists the alarm company guard in resetting the alarms that have been activated and turns off the lights. Both depart the premises through the point of entry in the company of the police and return to their respective stations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

If it is determined that **an actual burglary attack** has taken place, the police officers radio or telephone for additional officers and other assistance.

Additionally, the interior and exterior areas are searched thoroughly for hidden or fleeing intruders; damage, if any, to the vault is repaired; the alarm system is restored and reset; and appropriate surveillance is established to detect any hidden or returning criminal activity. In the event that the burglary is discovered in the absence of police at the scene, the supervisor immediately contacts them to report the crime and request their prompt assistance. In addition, the local DEA office is promptly notified and DEA Form 106 is prepared and filed in accordance with DEA regulations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

Note: Many states require that a report be submitted to the board of pharmacy or other agencies with enforcement jurisdictions.

If the controlled substance vault has been physically penetrated or forced open, the supervisor **must remain at the premises** in charge of the scene until the structure or door is restored to normal or the warehouse reopens on the next business day. This is required despite the restoration of the alarm system since a vulnerability to a hit-and-run burglary would exist until the "physical security" has been restored.

If, for any reason, the alarm system cannot be restored to full normal operation, the supervisor must see to it that the following steps are taken:

- The supervisor remains at the scene and requests assistance, if necessary, from other company supervisors;
- The alarm company guard or service personnel responding to the alarm are requested to stay at the premises until the alarm system has been repaired and restored; and
- If the alarm system still cannot be restored, then the supervisor secures the services of alarm company guards, off-duty police officers, contract security guards or other

appropriate security forces to maintain watch on the premises until security against burglary or robbery can be fully restored.

Note: Under such circumstances, there is a vulnerability relating to the safety of the supervisor and others who may remain on duty at the premises. Precautions that should be taken include locking all perimeter doors and windows, requesting that the police return frequently on a patrol basis, and requiring that the supervisor remain in frequent telephone contact with another supervisor located outside the premises at a safe point. In some instances, commercial telephone circuits may be out of order. In such case, the use of portable radio equipment and cellular phones may be required together with procedures for two-way communication between supervisors and/or the alarm company central station and the police.

- When full security has been restored, division management should review the incident to evaluate the cause and any improper or unsafe actions taken by responding personnel, and revise security procedures where appropriate to provide a more effective and safer response to a similar incident. On the day following the restoration of service, the alarm company is required to have a service supervisor thoroughly test the entire system and certify that the alarm system has in fact been restored to its original condition.

Alarm Related Procedures for Police Connect Alarm System Supervision and Response

Alarm systems connected directly to a police station or municipal communications center that is manned on a 24-hour basis require essentially the same response from the supervisors assigned such duties. The variations in response conditions are as follows:

- On receipt of a phone call from the police, the supervisor contacted requests the name and identification number of the police officer calling. The supervisor then recalls the commercially listed number of the police agency and verifies the authenticity of the call prior to departing the safety of his/her residence.
- On arrival at the warehouse, the supervisor verifies the presence of a police officer or proceeds as previously instructed to again call the police to the scene prior to entering the premises.
- When search and entry of the premises are completed, the supervisor restores the alarm circuits and departs with the police officer.
- In the event that the alarm system cannot be restored, the supervisor contacts the 24-hour telephone number of the alarm company (if available) and requests a service man to respond immediately to the premises to repair, adjust or otherwise restore the alarm system. If feasible, the supervisor should request that the police officers remain at the scene until the alarm company service representative arrives.
- An **Incident Report (Form #15)** should be completed and sent to the Corporate Compliance Department.

ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access **(Exhibit B).**

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

> "The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." **(21 CFR 1301.72(d))**

Division management maintains an **Access and Surveillance List (Form #16)** of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a **"Restricted Area" (Exhibit C)** sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

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PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. **Refer to Drug Thefts/Losses within Required Reports to DEA.** The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to **21 CFR 1301.74 (e)** upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them.

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form -DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item. The **Selected Item Audit Report (Exhibit I)** gives all movement - purchases, returns, sales and inventory adjustments - for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with **21 CFR 1301.90** and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. **Delivery Vehicle Security Rules (Form #17)** are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do no indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

Durability A seal must be strong enough to prevent accidental breakage during normal use.

Design The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

Tamperproof The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

Individually Identifiable Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

Time of Application Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

Verification Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log.

Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a **Will Call Log (Form #18)** that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a **Pre-Employment Waiver (Form #19)** consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a **Post-Employment Security Data Information Sheet (Form #20).** The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the **Test for Distribution Center Employees Handling Controlled Substances (Appendix B)** as well as the **Post-Employment Security Data Information Sheet.** The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they should notify their supervisor immediately. DEA regulations regarding this should be posted in the facility **(Exhibit D).**

- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.

- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.

- Protection of Company property is a responsibility all employees must share. Any employee discovering theft, loss, or malicious damage has an obligation to report the incident immediately to his supervisor.

- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.

- Tampering with or breaching Company security systems or policies is prohibited.

- Theft or unauthorized removal or use of Company or another employee's property is prohibited.

- Possession of firearms or illegal weapons on Company property is prohibited.

- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.

- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.

- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.

- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect should be posted throughout the distribution center **(Exhibit E).** Random periodic inspections could serve as a deterrent to internal theft.

- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.

- Visitor's entering the distribution center should be asked to sign in on a **Visitor's Log (Form #21),** indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.

- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.

- Coats and pocketbooks are not allowed in the warehouse.

- Employees are to adhere to the posted access list for the cage and vault area.

- A **Miscellaneous Security Log (Form #22)** should be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled **Violence Prevention Procedures (Exhibit G)** should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that **all** employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
- In the event of a robbery:
  a. Offer no resistance.
  b. Stay calm.
  c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

INSPECTIONS OVERVIEW

Overview

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (the Controlled Substances Act") authorizes the Drug Enforcement Administration (DEA) to enforce provisions of the act as they apply to registered handlers of controlled substances. The stated DEA goal is *"to significantly reduce the availability of licitly produced drugs used for illicit purposes in the United States."*

The act establishes a comprehensive system to control the manufacture and distribution of controlled substances necessary for legitimate medical needs. Since the controlled substances in question include some of the most potent drugs known to man, the incentive to divert these drugs into the illicit market is great. Drug related deaths and injury statistics indicate that legally produced controlled substances account for a large percentage of drugs associated with drug abuse injuries reported by hospital emergency rooms. In fact, 15 of the top 20 controlled substances reported in hospital emergency room mentions were pharmaceuticals legally available in the United States market.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances and for investigating diversion of these substances into the illicit market. The Diversion Control Program prevents, detects, and investigates the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs. To achieve this goal, DEA's diversion program uses programs designed to maximize the effect of criminal, civil and regulatory investigations and controls intended to limit the availability of diverted substances.

The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; an organized system of drug destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

These activities are designed to meet DEA's responsibilities under the Controlled Substances Act and to prevent the diversion of controlled substances from legitimate distribution channels. When violations are discovered, appropriate action (administrative, civil or criminal) will be considered.

As we move further into the 1990s, the pharmaceutical industry is facing an increasingly active enforcement and regulatory climate.

DEA registrants must be aware of this climate, and ensure that they are in full compliance with DEA requirements or take immediate corrective action before DEA investigates their facility.

Notice of Inspection

Cardinal Health recognizes the fact that federal and state regulatory agencies have explicit authority to inspect our premises and records.

Upon notice of a federal or state regulatory inspection, contact the Corporate Compliance Department immediately and advise to the nature of the visit, names of the officials and the agency they represent. The Department can be of assistance in helping to verify an individual's identification if the need arises.

Full cooperation must be given to the inspecting authorities. However, only persons authorized by division management may answer questions posed by the regulatory inspector. Inspections should be monitored closely by qualified Cardinal personnel, and a daily detailed written record in the inspection must be prepared.

Upon arrival of the investigators at the registered location, the manager, his/her designated alternate and the individual who has overall responsibility for controlled substances should meet with the investigators as soon as possible, review their credentials (a picture of the person on an official ID Card)and accept the DEA Notice of Inspection. Inspector(s) should be asked to sign the Visitor's Log and given a Visitor Badge to be worn at all times. A discussion should then be held regarding the purpose and extent of the investigation and the desire of management for a close-out discussion at the completion of the investigation. **(21 CFR 1316.05)**

If you are not sure that the individual requesting entry is a bona fide city, state, or federal official do not allow them to enter the distribution center. Request information as to whom they report (their immediate supervisor) and how (telephone number) you can verify their identification.

Note:Receptionist should not admit inspector(s) into facility or accept their credentials.

Authority of the DEA Investigator

21 USC 880 and **21 CFR 1316.03** allow DEA investigators to enter a registered location (controlled premises) upon stating their purpose and presenting credentials and a written notice of inspection or, if warranted, an administrative inspection warrant for the purpose of:

- Inspecting and copying records, reports and other documents required to be kept or made;
- Inspecting, within reasonable limits and in a reasonable manner, all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Controlled Substances Act;
- Conducting a physical inventory of all controlled substances on the premises;
- Collecting samples of controlled substances pursuant to DEA Form 84; and
- Checking records and information regarding the distribution and receipt of controlled substances by the registrant.

Exclusion From Inspection

Unless consented to in writing by the registrant, no inspection authorized by 21 USC 880 and the implementing regulations should extend to:

- Financial data;
- Sales/receipt data other than shipping and receiving data; or
- Pricing data.

Entry to Premises

DEA officials will conduct the investigation. The officials have the right to enter the registered premises and conduct the investigation at reasonable times in a reasonable manner once they state their purpose, present their credentials and written notice of their inspection authority (DEA Form 82) to their responsible registrant official, and receive informed consent or present an administration inspection warrant.

An administration inspection warrant is not required if informed consent is obtained from the registrant. Whenever possible, the informed consent should consist of a written statement (DEA Form 82 with addendum— language found in Section 1316.08) signed by the registrant.

Investigation

An individual (preferably a responsible officer or employee) who is familiar with the DEA record keeping and reporting requirements and security in place at the facility always should accompany and monitor the investigators.

This individual should be prepared to:

- Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the areas;
- Explain the operation/type of security, record keeping and reporting systems/procedures maintained;
- Assist the investigators;
- Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of the records reviewed;
- Obtain copies for and retain copies of any documents the investigators request;
- Assure that information volunteered is clearly beneficial to the wholesaler;
- Assure no misrepresentations are given to the investigators;
- Note any suggestions or criticisms expressed by the investigators. Any violations discovered in this manner should be corrected immediately and documented; and
- Complete a daily detailed written record of inspection that includes the following:
  - any questions raised by the inspector,

- any questions raised by the monitor,
- any requests made by the inspector,
- what the inspector was shown,
- a list of any records viewed or copied by the inspector,
- items inventoried and verification of the inspector's counts,
- any suggestions of criticisms expressed by the inspectors,
- complete a **DEA Inspection Report (Form #23)** and forward to Corporate Compliance Department.

Note: The registrant using this report and statements made by the investigator should reconstruct the investigation to verify any violations or, as is possible, reveal no violations.

All personnel are instructed not to read, acknowledge in any way, or sign any affidavit presented to any Company employee by an investigator.

Discussion with Management (Close Out)

This phase will be used by DEA to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by non-acceptance of the violations. Explain that Cardinal Health, Inc. employs a Director of Compliance and inquire if the results of the inspection warrants his presence at the exit interview. If yes, contact the Director of Compliance immediately. If the DEA intends to take further action, the registrant may or may not be informed of what courses of action are possible. The registrant will not be informed of the specific action to be recommended.

*Note: DEA is **not required** to conduct a closing discussion at the completion of the investigation. If not initiated by the investigator, the registrant should request a closing discussion at the convenience of the investigator. If this fails, it is suggested that a request be made in writing to the investigator's supervisor, expressing the desire to meet and discuss the findings and any corrective action that may be required.*

If a closing interview is held, the investigator may advise the registrant of any violative conditions. If the registrants cannot obtain a closing discussion, the report prepared by the employee(s) assigned to accompany the investigator during the investigation should be utilized to reconstruct the investigation and findings.

Once aware of any violations, the registrant should take the following initiatives in seeking and implementing corrective actions:

- Reconstruct the investigation and findings, using the same documents, facility review utilized by the investigators and the registrant's internal report.
- Take appropriate action to correct any violations or problems uncovered during the DEA investigation; and
- Convey to DEA the corrective action taken, what steps the registrant has taken to prevent future problems and inquire what further action the registrant should take.

It is suggested that if a registrant's investigation disagrees with the DEA investigation, they should contact DEA immediately and request a meeting to discuss the findings.

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DISTRIBUTOR ACCOUNTABILITY INVESTIGATIONS PROCEDURES

An investigation is divided into four phases: preparation, on-site, follow-up and past history. The information sought by the DEA during each phase is outlined below.

Preparation

Prior to inspecting a facility, the registrant files at the respective DEA location are reviewed; i.e., review of ARCOS reports, review of registration categories and schedules, etc.

On-Site Investigation

Initial Phase

The initial phase involves initial discussion, presentation of investigator credentials and notice of inspection (if a warrant is used, the registrant should consider the need for an attorney). The credentials and notice will be presented to that person who has managerial responsibility for operating the firm. The investigator should state the purpose and indicate the scope of the investigation.

Management at this time should request that the investigators advise them of any violations discovered during the investigation so that corrective action can be taken immediately. Management should state that they desire a closing discussion at the completion of the investigation.

Background Information

The DEA investigators will want to know the:

- Names, addresses, date of birth and social security numbers of corporate officers and/or owners of the registrant and identification of individuals responsible for record keeping and security;
- Number of employees and appropriate registration (federal, state and local); and
- Percentage of business dedicated to controlled substances.

They also will want to review reporting procedures regarding thefts, losses or destruction of controlled substances.

A completed copy of the **DEA On-site Background Information Package (Form #28)** can provide the DEA Inspectors with pertinent company information.

Closing Inventory

The closing inventory is usually taken before or after business hours, so that no adjustments for transactions outside the accountability period are necessary. An accurate inventory is necessary and advantageous. All shipping, receiving and return areas, as well as other areas where controlled substances might be stored, should be checked.

A responsible employee of the registrant should verify the accuracy of the inventory and make a copy for the registrant's records.

Initial Inventory

An actual inventory taken by the registrant, an inventory from a previous DEA investigation or a computer inventory printout may be utilized if the registrant will attest to its accuracy.

Regardless of the inventory used, the required biennial inventory will be reviewed.

Receiving Records

Order forms will serve as the primary record of documenting the receipt of Schedule II controlled substances. They also will be reviewed for accuracy.

The power of attorney will be reviewed.

ARCOS reports and purchase invoices will be reviewed to verify accuracy of the order form transactions for Schedule II controlled substances and Schedule III narcotic controlled substances.

Receiving records which record supplier's name, address, and DEA number; name of controlled substance; strength; quantity received; and date of receipt for Schedule III through Schedule V will be reviewed. These records must be kept in a readily retrievable manner. The registrant will be required to attest to the accuracy of the records.

Sales Records

Order forms will serve as the primary record documenting the sale of Schedule II controlled substances. They also will be reviewed for accuracy.

Registration of customers will be verified.

A sampling of ARCOS records and customer sales records for Schedule II controlled substances and Schedule III narcotic controlled substances will be reviewed to verify shipments.

The quantity of Schedule III through Schedule V controlled substances distributed may be determined from a number of different types of records. The primary record is the distributor's sales invoice.

Sales will include all dispositions from inventory, including documented and reported thefts, returns and destructions.

Credits and Returns

A review of credit memoranda will be made to determine that there was physical movement of controlled substances or credit.

Returned controlled substances will be inspected to verify that there is documentation showing returns, disposition by destruction or return to inventory.

Note: If the registrant has another record keeping system, such as the computerized Selected Item Audit Report which contains all required information and attests to its accuracy, these records may and should be used.

ARCOS

Reports will be verified by comparing them to other purchase and sales records.

Accountability

The initial inventory is combined with all receipts (including returns) of controlled substances and compared to the closing inventory plus sales, destructions, returns, reported thefts or losses accounted for by the registrant from its records.

Security

This evaluation will include:

- Review of location, crime classification, building construction, access restrictions and storage areas, including size and type of physical security systems in place;
- Evaluation of alarm systems and test;
- Review of security and procedures employed in shipping and receiving areas, picking areas, and packaging areas;
- Review of procedures for determining proper registration of customers;
- Review of frequency of alarm checks and procedures for key control, after hours entry, badge system and lock changing; and
- A review of the registrant's system for monitoring unusual and excessive orders.

Discussion with Management

This will be used to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by nonacceptance of the violations. If DEA's intention is to take further action,

the registrant may be informed of courses of action possible, but not the specific action to be recommended.

Note: DEA is ***not required*** *to conduct a closing discussion at the completion of the investigation. In this case, the registrant should request a closing discussion at the convenience of the investigator. If the request is not successful, it is suggested that the registrant send a written request to the investigator's supervisor, expressing the desire for a meeting to discuss any findings and corrective action which may be required.*

Follow-Up Investigation

After the on-site portion of the investigation is completed, a verification of purchases and sales most likely will be performed. The extent of the verification will depend upon the nature of the investigation and discrepancies found. In addition, DEA may conduct file checks on all persons who are interviewed during the investigation.

History of Violations

The registrant's history if violations will be taken into consideration by DEA in determining the type of action to be levied against the registrant.

VIOLATIONS

The DEA will take action against a registrant in all instances where an investigation reveals violations of the Controlled Substance Act and the implementing regulations. The **Table of Offenses and Penalties (Exhibit H)** summarizes these violations.

Administrative Actions

Revocation of Non-Practitioner Registration or Application Denial

DEA registration or application may be revoked, suspended or denied if at least one of the following conditions is present:

- The application for registration has been materially falsified;
- The registrant (owner, officer, controlling stockholder) has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
  1. Maintenance of effective controls against diversion,
  2. Compliance with applicable state and local law,
  3. Prior conviction record relating to controlled substances,
  4. Registrant's violative history,
  5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle controlled substances has been suspended, revoked or denied.

"No Automatic Renewal" of Registration

To prevent renewal of the registrant's registration, the DEA will place an administrative code on the registration.

This procedure is usually utilized to suspend approval of the renewal application when the investigation shows that the registrant has failed to maintain adequate controls against diversion and grounds for denial exist.

The registrant is authorized to continue operating on a day-to-day basis until final action is taken (voluntary surrender, denial of renewal application or removal of the administrative code).

Letter of Admonition

The letter of admonition advises the registrant of the violations found and documents these violations in written form. This allows for voluntary, corrective actions by the registrant and makes the violations a matter of record should the same violations be encountered at a later date.

Administrative Hearing

A hearing will be held when the severity of the violations and the registrant's attitude toward them render the letter of admonition ineffective. An administrative hearing provides DEA and the registrant with the opportunity to explain their respective views on the violations and to discuss the necessary corrective actions.

Order to Show Cause

An order to show cause may be issued to a registrant for denial, revocation or suspension of a DEA registration for one of the following factors:

- The application for registration has been materially falsified;
- The registrant has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
  1. Maintenance of effective controls against diversion,
  2. Compliance with applicable state and local law,
  3. Prior conviction record relating to controlled substances,
  4. Registrant's violative history,
  5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle con-trolled substances has been suspended, revoked or denied.

During a show cause hearing, the registrant has the opportunity to explain why the registration should not be suspended or revoked.

Civil or Criminal Prosecution

The use of civil or criminal prosecution will be determined by the severity of the violations found during the investigation and discussions with DEA management and the assistant U.S. attorney.

The determination between civil and criminal prosecution is made based upon the registrant and/or person knowingly or intentionally committing the violation(s).

Civil penalties are assessed at $10,000 per violation.

Cardinal Health

Guide to Handling ARCOS Transactions

Guide To Handling ARCOS Transactions

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GUIDE TO HANDLING ARCOS TRANSACTIONS

Introduction

The Automation of Reports and Consolidated Orders System (ARCOS) was developed by the DEA to report inventories of selected controlled substances and increases and decreases to these inventories. The selected controlled substances are Class II and III narcotics.

Transactions can be reported electronically via tape or diskette, or manually using ARCOS Form 333. In most divisions, a majority of the ARCOS records are created automatically during the receiving, invoicing and crediting processes. Other records must be created by manually entering the data into the ARCOS Maintenance Menu.

A report of all ARCOS transactions generated by the system is available for review. Depending on the system, this may be daily or monthly. Prior to submission to ARCOS, erroneous transactions can be changed or corrected using the ARCOS Maintenance Menu.

Distributors are required to take an annual inventory of each reportable controlled substance on December 31st and file it with ARCOS no later then January 15th of the following year. Increases and decreases in the inventory of each reportable controlled substance must be reported on a monthly basis and filed with ARCOS no later than the 15th of the month following the end of the reporting period.

For automated reporters, a tape of these transactions is sent to ARCOS, with a hardcopy report maintained at the division for two years. This report is useful when researching errors identified by ARCOS as it contains additional information, including item number and description, invoice number and customer or vendor number. For manual reporters, hand-written transactions are submitted to ARCOS on Form 333. One copy of the form is maintained at the division for two years.

ARCOS 'reads' the tape and generates a report entitled "ARCOS Daily Transactions Processing Error Report." The report will either acknowledge that no errors were found, or will list the transaction records in error, with the error code, description of the error and a correction number. Corrections must be made and the transactions resubmitted. Error reports should be maintained at the division for two years.

All media submitted to ARCOS should have a barcode label attached. Submissions should be made as described below:

ARCOS reports sents via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

Inquiries can be made to the ARCOS Unit at (202) 307-8600.

What to do before sending a report to ARCOS

The Distrack system has a daily report of ARCOS transactions, while the HP generates the report at month-end. Each system has the ability to make changes, additions and deletions prior to the submission of the transactions to ARCOS. Instructions can be found in the ARCOS Maintenance Section.

In the review process, look for

- DEA numbers that do not fit the typical format (2 letters followed by 7 numbers),
- blank numbers that do not fit the typical format (9 digit number),
- items that are not ARCOS reportable,
- quantities that appear to be excessive or out of the ordinary, and
- inventory adjustments.

Keep in mind that the only transactions that need to be reported to DEA are those that document an actual transfer of product. Records created by inventory adjustments when the product is moved from the live inventory to the morgue inventory do not represent a transfer of product and should be deleted. Credit and rebills for contract/chargeback purposes and dropship billings are two more examples of financial transactions that do not represent the actual transfer of product.

If changes need to be made to an Associate's DEA registration number, the modification should also be made in the Customer or Vendor Master File so that future transactions do not contain the same error.

ARCOS reportable items that are documented as lost-in-transit or stolen on DEA Form 106 or as destroyed on DEA Form 41, need to be reported as transactions to ARCOS. Since forms to the DEA are submitted manually, ARCOS records are not generated by the system and need to be created.

For an item lost-in-transit,
- use the date of the sale,
- the NDC and quantity of the item,
- the associate DEA number as the original sale record,
- a transaction code of X.

For a theft,
- report the date the theft occurred or was identified,
- the NDC and quantity of the item,
- a transaction code of T.
- The associate DEA number should be left blank.

For a destruction of a controlled substance (destroyed at your registered location),
- use the date the destruction occurred,
- the NDC and quantity of the item,
- a transaction code of Y
- the associate DEA number for the regional DEA office.

Product sent to a third-party for destruction are documented as a sale to the company. ARCOS records should be created through the invoicing process using transaction code S.
If these activities occurred during a previous month, they should be reported as late transactions using the I code in the Action Indicator column.

ARCOS reportable items that are returned from an unknown source need to be documented as an addition to the inventory. This record is not generated by the system and needs to be created.

For an unsolicited return,
- use the date the product was received at the facility,
- the NDC and quantity of the item,
- a transaction code of V,
- the associate DEA number of UNKNOWN

The following are some sample lines from a report from the Distrack system., with a summary of what it means.

GRR050

THE MUNSTER COMPANY

ARCOS TRANSACTION EDIT REPORT
DAILY TRANSACTIONS CALLED FOR BY SYC593 - END OF DAY PROCESSING
PERIOD ENDING 3/19/98

TRANSACTION YYMM	IDENT.	CDE	DATE	ITEM NUMBER	NDC NUMBER	DESCRIPTION	ASSOC. ID NO.	ASSOC. DEA REG. NO.	BLANK FORM NO.	CORRECTION NUMBER	D C	QTY	BILL-ACCT #	SHIP-ACCT#	INVOICE NUMBER	INVOICE DATE	MFG#	PO#	ADJ	C/M#	SRC
9803	6499	P	3/19/98	181084	00034-0517-25	MS CONTIN CR 100MG 25UD PFC C2	5570	PT0226820	973652612			12	000000	000000	0000000	0/00/00	05570	49623		0000000	
9803	6503	S	3/19/98	104334	00074-3142-01	NEMBUTAL SOD 18.2MG 480ML C2		UNKNOWN				1	000000	000000	0000000	0/00/00	05000	00000	50	0000000	
9803	6650	S	3/19/98	148976	59630-0100-04	PROTUSS 120ML GRAPE HOR C3	381914	AB3010763				2	381914	381914	4207012	98/03/19	00000	00000		0000000	

Field Name	Description	Definition	Function
YYMM	year and month	4 digit code to identify the year and month of the reporting period	reported to ARCOS to identify the reporting period
IDENT	transaction identifier	sequential number assigned by the reporting registrant to each transaction record	reported to ARCOS to identify the transaction
CDE	transaction code	single-character field which identifies each specific ARCOS-reportable activity. The entire list of available codes is on the next page.	reported to ARCOS to identify the activity
DATE	transaction date	the actual date on which the activity occurred	reported to ARCOS to identify the date of the activity
ITEM NUMBER	item number	number assigned by the company to a particular SKU	used by the division for research and identification purposes
NDC NUMBER	National Drug Code number	11-character code that identifies controlled substance products	reported to ARCOS to identify the item
DESCRIPTION	item description	description of the item including size, strength, and finished form	used by the division for research and identification purposes
ASSOC. ID NO.	associate identification number	number assigned by the company to the vendor or customer participating in the transaction	used by the division for research and identification purposes
ASSOC. DEA REG. NO.	associate DEA registration number	9-character field identifying the customer or supplier with which the transaction took place	reported to ARCOS to identify the other party in the transaction
BLANK FORM NO.	narcotic order form (DEA 222) number	9-character field for the number of the order form	reported to ARCOS for CII items
CORRECTION NUMBER	correction number	unique sequential number assigned by ARCOS to an erroneous transaction	reported to ARCOS for reprocessing a corrected transaction
DC	action indicator (formerly the delete indicator)	a single character field which initiates three different ARCOS data base operations	reported to ARCOS when deleting or revising previously submitted and accepted transactions, or when inserting unreported transactions from previous months.

Field Name	Description	Definition	Function
QTY	quantity	numeric field containing the number of packages, weight, or volume being reported	reported to ARCOS to identify the quantity
BILL – ACCT #	Bill-to account number	customer number assigned by the company to the account that was invoiced for the product(s) in this transaction	used by the division for research and identification purposes
SHIP – ACCT #	Ship-to account number	customer number assigned by the company to the account that was delivered the product(s) in this transaction	used by the division for research and identification purposes
INVOICE NUMBER	invoice number	the number assigned to the invoice that reflects the sale to the customer	used by the division for research and identification purposes
INVOICE DATE	invoice date	the date the invoice was created. Usually matches the transaction date.	used by the division for research and identification purposes
MFG #	vendor number	number assigned to the vendor from whom the product was purchased	used by the division for research and identification purposes
PO#	purchase order number	number assigned to the order under which the product was purchased	used by the division for research and identification purposes
ADJ	inventory adjustment code	the code assigned to the adjustment to indicate the disposition of the inventory	used by the division for research and identification purposes
C/M#	credit memo number	the number assigned to the credit memo that reflects the return of the product from the customer	used by the division for research and identification purposes
SRC	source	identifies where the information came from that created the transaction record	used by the division for research and identification purposes

TRANSACTION CODES
(FROM PAGE 5-6 OF THE ARCOS REGISTRANT HANDBOOK)

INVENTORY TRANSACTION CODES

1	SCHEDULE CHANGE INVENTORY
3	YEAR-END INVENTORY
4	YEAR-END IN-PROCESS INVENTORY (MANUFACTURERS ONLY)
5	SPECIAL INVENTORY
8	NO YEAR-END INVENTORY

ACQUISITION TRANSACTION CODES (INCREASES TO INVENTORY)

P	PURCHASE OR RECEIPT
R	RETURN
V	UNSOLICITED RETURN
W	RECOVERED WASTE (MANUFACTURERS ONLY)
M	MANUFACTURED (MANUFACTURERS ONLY)
G	GOVERNMENT SUPPLIED
L	REVERSING (MANUFACTURERS ONLY)
J	RETURN OF SAMPLE TO INVENTORY (MANUFACTURERS ONLY)

DISPOSITION TRANSACTION CODES (DECREASES TO INVENTORY)

S	SALE, DISPOSITION, OR TRANSFER
Y	DESTROYED
T	THEFT
N	NONRECOVERABLE WASTE (MANUFACTURERS ONLY)
U	USED IN PRODUCTION (MANUFACTURERS ONLY)
Z	RECEIPT BY GOVERNMENT (SEIZURES, SAMPLES, ETC.)
Q	SAMPLING (MANUFACTURERS ONLY)
K	USED ON PREPARATIONS (MANUFACTURERS ONLY)

MISCELLANEOUS TRANSACTION CODES

F	REORDER DEA-333 FORMS
X	LOST IN TRANSIT
7	NO ARCOS ACTIVITY FOR THE CURRENT REPORTING PERIOD

What To Do When A Report Is Received From ARCOS:

1. Place the ARCOS template over the error report to separate the columns of information.
2. Identify the time period of the errors.
3. Retrieve the monthly report for that time period, to be used as reference.
4. Review the error code and the necessary correction action.
5. Determine if the error needs to be resubmitted. (Is it an ARCOS reportable item? Does the record reflect an actual transfer of product?)
6. Research any information pertinent to the type of error (invoice, receiver, credit memo, narcotic blank, etc.)
7. Create correction transactions in the ARCOS Maintenance Menu of the computer system. These transactions should be made in the current month's tape and not in the month of the original submission.
8. Make any necessary changes to the customer/vendor file or item file that could prevent future errors.

EDIT ERRORS REPORT

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
A R C O S - 2
DAILY TRANSACTIONS PROCESSING

ERROR REPORT

THE MUNSTER COMPANY
1313 MOCKINGBIRD LANE
TRANSYLVANIA, PA 66613

ERRORS FOR CONTROL RECORD = = > RM1313666*043098M

RM1313666S 5045800340500000192 RD010495998047570704289800000102000009804011749
E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION.
CORRECTION NUMBER: 00000102

RM1313666P 0000802580100000020 PA30379829621567550407980000010300009804012347
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00000103

Errors for Control Record

RM1313666	SUBMITTING REGISTRANT NUMBER
*	ASTERISK
043098	LAST DATE OF THE REPORTING PERIOD REPORT MEDIA (T=TAPE)
M	REPORTING FREQUENCY (M = MONTHLY)

LINE 1

RM1313666	REPORTING REGISTRANT NUMBER (DIVISION)
S	TRANSACTION CODE
50458003405	NATIONAL DRUG CODE (11 DIGITS)
00000192	QUANTITY (8 DIGITS)
RD0104959	ASSOCIATE REGISTRATION NUMBER (CUSTOMER OR VENDOR)
980475707	DEA ORDER FORM NUMBER (BLANK NUMBER, 9 DIGITS)
042898	TRANSACTION DATE
00000102	CORRECTION NUMBER
00009804	YEAR/MONTH OF REPORT
011749	TRANSACTION IDENTIFIER

LINE 2

E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA RESGISTRANT NUMBER

LINE 3

CORRECTION NUMBER: 00000102

ERROR CODES
(FROM PAGE 7-5 OF THE ARCOS REGISTRANT HANDBOOK)

E01 REPORTING REGISTRANT NUMBER DOESN'T MATCH THE ONE ON THE CONTROL RECORD
E06 DELETE INDICATOR FIELD MUST BE BLANK OR MUST BE THE LETTERS "A", "D", OR "I"
E07 DELETE INDICATOR FIELD MUST BE BLANK IF A CORRECTION NUMBER IS PRESENT
E12 TRANSACTION DATE CONTAINS AN INVALID MONTH AND/OR AN INVALID DAY
E13 TRANSACTION DATE MUST BE THE LAST DAY OF THE REPORT MONTH OR QUARTER
E14 TRANSACTION CODE REQUIRED A YEAR-END DATE IN THE TRANSACTION DATE FIELD
E15 TRANSACTION DATE IS LATER THAN THE RUN DATE OF THE ARCOS 2 EDIT PROGRAM
E16 TRANSACTION DATE IS NOT WITHIN THE REPORTING REGISTRANTS REPORT PERIOD
E17 TRANSACTION DATE ISN'T WITHIN THE 2 YEAR DATE RANGE OF THE ARCOS SYSTEM
E21 CORRECTION NUMBER ENTERED IN INVALID. IT MUST BE NUMERIC
E22 CORRECTION NUMBER IS NOT IN THE ERROR FILE
E25 THE ARCOS EDIT STILL FOUND ERRORS ON THE CORRECTION TRANSACTION
E28 DATA ENTERED IN THE QUANTITY FIELD IS INVALID. IT MUST BE NUMERIC.
E31 THE UNIT VALUE ENTERED CANNOT BE USED WITH THE ENTERED NDC NUMBER
E32 UNIT VALUE MUST BE BLANK, "D", "K", "1", "2", "3", "4", "5", "6"
E35 STRENGTH MUST BE BLANK FOR BULK FINISHED OR 0001 TO 1000 FOR BULK RAW
E36 STRENGTH IN INVALID. STRENGTH MUST BE BLANK OR NUMERIC
E40 TRANSACTION CODE IS INVALID. SEE THE ARCOS MANUAL FOR VALID CODES.
E41 TRANSACTION CODE IS RESERVED FOR DRUG MANUFACTURERS ONLY
E42 TRANSACTION CODE REQUIRES ASSOCIATE REGISTRANT NUMBER TO BE BLANK
E43 ASSOCIATE REGISTRANT NUMBER REQUIRES TRANSACTION CODE "Y", OR "G", OR "Z"
E44 TRANSACTION CODE CONFLICTS WITH THE NDC NUMBER'S CSA SCHEDULE
E45 TRANSACTION CODE REQUIRES AN ASSOCIATE REGISTRANT NUMBER ENTRY
E46 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR TRANSACTION CODE "Y/G/Z"
E47 ASSOCIATE REGISTRANT NUMBER CAN'T EQUAL REPORTING REGISTRANT NUMBER
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
E49 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR THE TRANSACTION CODE
E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED
E53 THE ORDER FORM NUMBER IS REQUIRED FOR SCHEDULE 1 & 2 DRUGS
E60 TRANSACTION CODE 1 – AN INVENTORY RECORD ALREADY EXISTS
E61 TRANSACTION CODE 3 OR 8 – YEAR-END INVENTORY AMOUNT ALREADY EXISTS
E75 THE NDC NUMBER IS INVALID, IT CONTAINS ONE OR MORE SPACES
E76 THE NDC NUMBER IS NOT IN THE DRUG FILE
E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION

ARCOS Transaction Maintenance/AS400

Through the modified ARCOS Transaction Maintenance Menu, changes can be made not only to transactions from the current month, but also transactions to previous months. All of the maintenance must be done in the current reporting period to ensure that changes are added to the current month's tape.

Since transactions can now be from a variety of months (previous or current), the transaction ID will consist of the year/month (YYMM) and sequence number (Seq), as shown on the far left of each transaction.

Screen 1

From the ARCOS File Maintenance Menu, you must select the file type and enter the report reference date, as well as an access path. The file type can either be Monthly (M), Annual (A), or Special (S). A majority of the time, this selection will be M. The report reference date is the last date of the reporting period you have selected. For example, if you want to look at the records for May 1999, then you would enter M and 05311999. Through your selection of an access path, you make the determination of how the transactions are sorted. Entering a 'starting at' value can help to limit your search, but is not required. By leaving that field blank, the search will begin with the lowest value of your selected access path. The options for access path are:

1 = Corporate Item Number
2 = Blank Number
3 = NDC Number
4 = Customer Number
5 = Vendor Number
6 = DEA Number
7 = Sequence Number

Screen 2

After selecting the file type, the reference date, the access path and pressing enter, the next screen is displayed. The columns appearing on the screen are:

Sel = select transaction to update
Seq # = transaction ID
Trans Date = transaction date
Cd = transaction code
Dc = action indicator (only used for late, adjusted, and deleted transactions)
Cst/Vnd = customer or vendor number, depending on which access path was chosen
NDC/Item # = NDC or item number, depending on which access path was chosen
Quantity = transaction quantity
ASS Reg # = Associate registration number (DEA number of the other party involved in this transaction)
Blank # = order form number (required for CII transactions only)

If you choose a 'starting at' value in Screen 1, that equals a valid value for that access path, then that value will be highlighted in all of the transactions where it is included.

You can scroll through transactions with a higher value for the access path, but in order to view transactions with a lower value, you must enter another value into the 'start at' field at the top of the screen and press F8. This 'start at' value is associated with the access path code selected on Screen 1. To select an alternative access path, press F12 to return to Screen 1.

To make a change to a transaction, enter '2' in the 'Sel' column and press enter. This will display the Change/Delete Current window. Changes can be made to any fields that are underlined. After completing the changes, press 'enter' and the transaction will be verified for accuracy and will be updated in the file. This function can be used for any transaction in the current batch including the current month's transactions, as well as any added, late or corrected transactions that have been entered.

To delete a transaction, enter '4' in the 'Sel' column and press 'enter'. This will display the Change/Delete Current window. No information can be entered into this pop-up window. Press <enter> to accept the delete. This function can be performed for any transaction that is displayed in the current batch that is not already deleted, this includes the current month's transactions, as well as any added, late or corrected transactions that have been entered. Deleted transactions will be displayed with an 'X' in the Dc column.

To add (current month) transactions, press (F6). This will display the Add Transaction pop-up window will appear requesting the required information. After completing the window, press <enter> and the transaction will be checked for accuracy and a transaction ID will be assigned. This add function can only be used for transactions that have occurred in the current month. Adding transactions from previous months is done using F14.

To add late (previous months) transactions, press (F14). This will display the Late Transaction pop-up window will appear requesting the required information. *You must assign a transaction ID that includes the YYMM of the transaction and an original sequence number.* The YYMM *must* be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Late transactions will be noted with an 'I' in the Dc column. This function can only be used for transactions that have occurred in previous months.

To add corrected (DEA specified) transactions, press (F15). This will display the Correction Transaction pop-up window will appear requesting the required information. These transactions are identified on the ARCOS-2 Error Report. *The correction transaction record must contain 1) all the fields that were correct on the original submission including the original transaction identifier, 2) the corrected field(s), and 3) the correction number.* The YYMM *must* be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Corrected transactions will be noted with a correction number under the Corr# column. This function can only be used for transactions that have been identified as errors by the DEA and must not have occurred in the current month.

To adjust (previous months) transactions, press (F20) This will display the Adjustment, Deletion pop-up window will appear requesting the required information. This is to correct mistakes on previously submitted transactions. Once these are identified, wait until the error report is received from ARCOS. If the transaction appears on the error report, a correction must be made using F15. If the transaction does not appear on the error report and was accepted by ARCOS, an adjustment must be made using F20. The first record created will be coded 'D' in the Dc column. You will then be

prompted to adjust the transaction to reflect correct information. The second record will be coded 'A' in the Dc column.

To delete (previous months) transactions, press (F21) This will display the Delete, Previous pop-up window will appear requesting the required information. This is to delete transactions that were previously submitted but should not have been. The record will be coded D in the Dc column.

To unfold the screen, press (F10). This will expand a single transaction to two lines and include the customer name and the item description.

To select all transactions that meet a specified value in an access path, press (F7). This will put a '2' in the 'Sel' column. If the transactions span for more than one page, you must page forward to the last page of the highlighted transactions to select all of these transactions. If you press F7 without first paging forward, you will only select the specified transactions from the first page.

To mass update, press (F5). This will display the Mass Change pop-up window. From this window you have the option to change the NDC, DEA number or Blank number from the first transaction you selected to another value. It is recommended that mass changes only be made to the field that was selected in the access path.

ARCOS File Maintenance - HP

Overview

In General:
The ARCOS File Maintenance screen allows the user to enter ARCOS File corrections. The screen was developed to replace the manual submission of corrections on ARCOS FORM 333 which the DEA will no longer accept from registrants who submit monthly reports electronically.

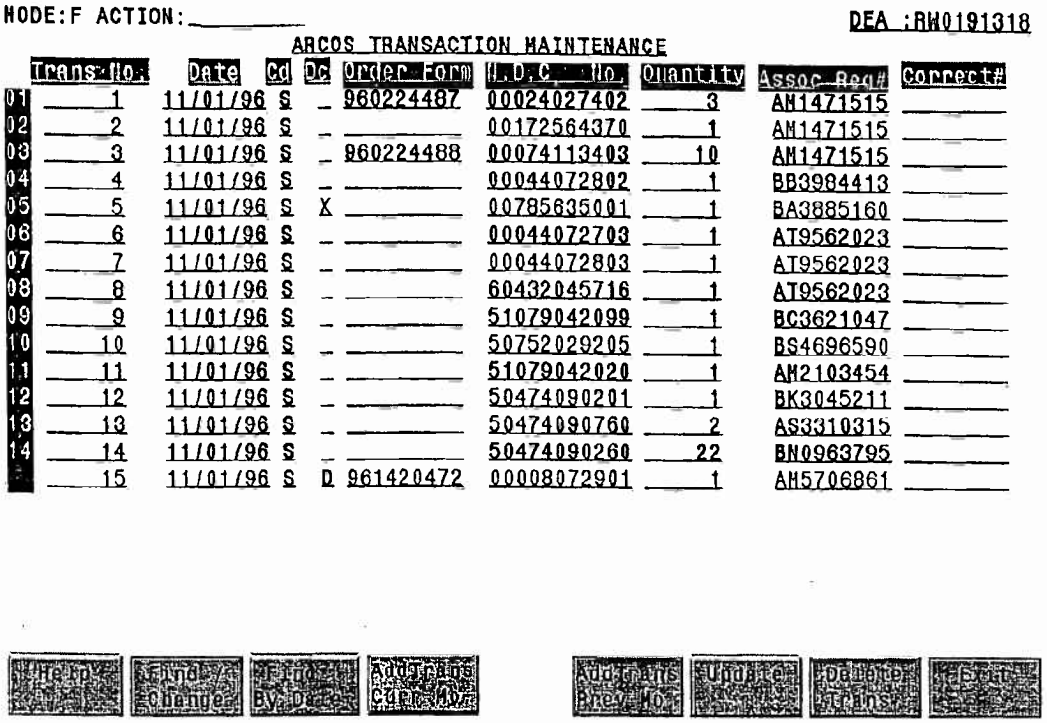
With the ARCOS file maintenance screen you have the ability to 1) make changes, additions and deletions to transactions prior to submission to ARCOS, 2) make adjustments, additions and deletions to transactions after acceptance by ARCOS, and 3) make corrections to transactions rejected by ARCOS.

Detailed Procedures

The ARCOS File Maintenance Screen is located on the **DEAMENUB.** To access **DEAMENUB,** log on to the live account and enter the following at the prompt: **MENU DEAMENUB**

Select option #11, ARCOS File Maintenance. This will take you to the ARCOS File Maintenance screen.

Note: Previous knowledge regarding the use of QUICK screens is needed to proceed with the following procedures.



MODE:F ACTION:_____ DEA :RH0191318

ARCOS TRANSACTION MAINTENANCE

	Trans No.	Date	Cd	DC	Order Form	D.E.A. No.	Quantity	Assoc Req#	Correct#
01	1	11/01/96	S	_	960224487	00024027402	3	AM1471515	
02	2	11/01/96	S	_		00172564370	1	AM1471515	
03	3	11/01/96	S	_	960224488	00074113403	10	AM1471515	
04	4	11/01/96	S	_		00044072802	1	BB3984413	
05	5	11/01/96	S	X		00785635001	1	BA3885160	
06	6	11/01/96	S	_		00044072703	1	AT9562023	
07	7	11/01/96	S	_		00044072803	1	AT9562023	
08	8	11/01/96	S	_		60432045716	1	AT9562023	
09	9	11/01/96	S	_		51079042099	1	BC3621047	
10	10	11/01/96	S	_		50752029205	1	BS4696590	
11	11	11/01/96	S	_		51079042020	1	AM2103454	
12	12	11/01/96	S	_		50474090201	1	BK3045211	
13	13	11/01/96	S	_		50474090760	2	AS3310315	
14	14	11/01/96	S	_		50474090260	22	BN0963795	
	15	11/01/96	S	D	961420472	00008072901	1	AM5706861	

Help F1 | Find Change F2 | Find By Date F3 | Add Trans Curr Mo F4 | Add Trans Prev Mo F5 | Update F6 | Delete Trans F7 | Exit F8

This is a standard QUICK screen which allows the user to enter information needed tocorrect ARCOS transactions.

The Screen starts in find mode. The Screen will request the Trans ID to find or the user may hit enter to scan the file.

To change transactions

Changes to transactions may be made using the Find/Change command (F2). Once a transaction has been selected either by transaction identifier or by line number, the date field is erased for change. If no change is required, press <enter> and the next field will be erased and the date will reappear. Continue this process through the entire line, making change(s) where needed. When completed with the line, press F6 to update the file. The change function can be used for any transactions in the current batch including the current months transactions, as well as any transactions added from previous months.

To add (current month) transactions

Transactions for the current month can be added using the Add Trans Curr Mo command (F4). The system will assign the next available transaction number. You will be required to add the rest of the information, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will only accept a date within the current month. To add a transaction from a previous month, use F5.

To add late (previous months) transactions

Transactions for previous months can be added using the Add Trans Prev Mo command (F5). You will be required to assign the transaction number using the next sequential number for that previous months batch. You will also be required to add the rest of the information for that transaction, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will require that the transaction date be from a previous month.

To delete transactions

Transactions from the current month can be deleted using the Delete Trans command (F7). You will be required to identify the transaction by transaction identifier or line number. The transaction will be coded with an 'X' and will be excluded from the tape. You must press F6 to update the file.

To delete (previous months) transactions

Transactions from previous months can be deleted by using a two step process of adding a previous months transaction and changing the code. First, add a transaction from a previous month using F5, keying in all of the required fields, pressing <enter> to tab through the fields. When the record is complete, you have the option of updating or changing it. To change the record, type the line number of the transaction (1) in the 'action' field, then change the 'I' in the Dc column to 'D'. Press F6 to update the file.

To adjust (previous months) transactions

Transactions from previous months can be adjusted by using a deletion from a previous month, in combination with a previous month add and a change of the code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. When the record is complete, change the code in the Dc column from 'I' to 'D'. Press F6 to update the file. A second transaction then needs to be added, containing all the fields that were correct on the original submission including the original transaction identifier, the corrected fields, and the correction number. When the record is complete, change the code in the DC column from 'I' to 'A'. Press F6 to update the file.

To add corrected (DEA specified) transactions

Transactions for correction can be done using a previous month add, including a correction number, then deleting the 'I' code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. Remember to include the correction number assigned to the transaction on the ARCOS Error Report. When the record is complete, remove the code in the Dc column. Press F6 to update the file.

Screen Definitions

Field Name	Field Description
Trans No.	The ARCOS Transaction Identifier.
Date	The transaction date, format of MMDDYY. Do not enter slashes the screen with auto format the field.
Cd	Transaction Code. When in this field use Function key <F1> "HELP" for a list of acceptable transaction codes.
Dc	Delete Indicator. This field is used to mark ARCOS transactions for delete. When in this field use Function key <F1> "HELP" for a list of acceptable delete codes.
Order Form	The Order Form Number
N.D.C. No.	The National Drug Code number.
Quantity	The Quantity.
Assoc Reg#	The Associated DEA Registration Number.
Correct #	The ARCOS Correction Identifier.

Screen Definitions

Function Key	Label	Function Key Description
F1	HELP	This will give Help on the screen when used in the Action Box and will give help for a specific field when used in that field.
F2	Find / Change	This is used to find transaction by a Trans ID or to scan the file. After finding a transaction, enter the line number of the transaction to modify the data in a field.
F3	Find By Date	This function key will allow the user to retrieve all the transactions for a specific date.
F4	AddTrans Curr Mo.	This will allow the user to add a transaction for the current month.
F5	AddTrans Prev Mo.	The will allow the user to add a transaction for a prior month.
F6	Update	After changing, adding or deleting any transactions this function key **MUST** be used to permanently save the transaction.
F7	Delete Trans	This function key is used to mark a transaction for delete.
F8	Exit	This key will allow the user to exit from the screen.

DEA
COMPLIANCE MANUAL

APPENDIX B

Test and Training Manual for Distribution Center Employees Handling Controlled Substances

TRAINING MANUAL FOR EMPLOYEES HANDLING CONTROLLED SUBSTANCES

TABLE OF CONTENTS

RECORDS AND REPORTS

PHYSICAL AND PROCEDURAL SECURITY

INSPECTIONS

INTRODUCTION

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotic and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drug and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Protection Control Act of 1970 (the "Controlled Substance Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The trust of this Controlled Substance Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- record keeping requirements;
- manufacturing quotas;
- distribution restriction;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable up to 15 years imprisonment and $10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances into the illegal market. The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; and organized system of destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

This manual is intended as a resource to the Controlled Substance Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has and tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs
Part 1300 to End – *available from:*

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual – *available from:*

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory. **Refer to Procedural Security for additional information on the Physical Verification of Controlled Substances.**

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Cardinal Health has received authorized from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the Drug Enforcement Administration by January 15th of the following year.

Periodic
(21 CFR 1304.11)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. **(21 CFR 1304.11 (d))**

> *Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.*

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

> *Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.*

Retention of Inventory Records. The record must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. **(21 CFR 1304.04)**

> *Note: State record keeping requirements may be more than two years and records should be maintained accordingly.*

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). **(Refer to DEA Correspondence 8/25/93).** The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current **DEA Certificate of Registration (Exhibit J).** DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration **(Exhibits K, L).** A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The **Quarterly DEA Exception Report (Exhibit N)** is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office will check this type of situation. Calls to the local DEA office should be documented on a **Regulatory Agency Contact Form (Form #1).**

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a **Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.**

Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. **(21 CFR 1301.51)**

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. **Refer to DEA Correspondence 8/25/93.**

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

W - Manufacturer

Y - Distributor

V - Retail Distributor

X - Importer

Z - Exporter

ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the **DEA Narcotic Blank Log (Form #4),** and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.

- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.

- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to **21CFR 1305.05(c).** The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

  Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log.**
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log.**
- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations **(21 CFR 1305.06).**
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

  Note: All three copies of voided order forms must be sent to the division.
- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3),** signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

  Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. ***Refer to DEA Correspondence 07-18-96.***

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green) the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.

- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.

- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

  Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

  Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. **Refer to DEA Correspondence 6/29/92.**

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit**, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. **Refer to DEA Correspondence 07-18-96 and 08-28-96.**

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.

2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.

3. Cardinal crossdock employee removes 222s from envelopes and **completes DEA222 Transmission Log** (Form #5).